K110913 SEP 23 2011

Section 5: Special 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Information:

Category	Comments
Sponsor:	ESTECH, Inc. 2603 Camino Ramon Suite 100 San Ramon, CA 94583 Tel: 925-543-2110
Correspondent:	Tamer Ibrahim Vice President ESTECH, Inc
Contact Information:	Tel: 925-543-2110 Fax: 925-866-7117
Device Common Name:	Electrosurgical cutting and coagulation device and accessories
Device Proprietary Name:	ESTECH Cobra Surgical System with ThermaShield accessory
Device Classification:	Class II, OCL (21 CFR 878.4400)

Predicate Device Information:

Predicate Devices:	ESTECH Cobra Surgical System (K051749)
Predicate Device Manufacturers:	Endoscopic Technologies, Inc (aka ESTECH)
Predicate Device Common Name:	Electrosurgical cutting and coagulation device and accessories
Predicate Device Classification:	21 CFR 878.4400
Predicate Device Classification Number:	Class II, OCL

b. Date Summary Prepared

31 March 2011

c. Description of Device

The ThermaShield is a flat, bell-shaped silicone pad that is designed to reliably fill the anatomic space between the target tissue of an RF ablation and adjacent non-target tissue. Its thickness and rounded edges provide tactile feedback to the surgeon and facilitates confidence in proper placement. The ThermaShield is primarily designed for use in open chest cardiac surgery.

The addition of the ThermaShield to the ESTECH Cobra Surgical System provides a more convenient option for the physician to thermally insulate surrounding non-target tissue during RF ablations. The ThermaShield is intended to improve upon

circumstances where no insulation is used or to replace the current use of a surgical glove as a thermal insulator between target and surrounding tissues (Williams, 2004; article in TAB 5).

d. Intended Use

The Estech Cobra Surgical System is intended for the coagulation of cardiac tissue using radiofrequency (RF) energy during cardiac surgery. The System can be used during general surgery to coagulate soft tissues. The System may also be used to coagulate blood and soft tissue to produce hemostasis.

e. Comparison to Predicate Device

The application ESTECH Cobra Surgical System with ThermaShield Accessory is identical in nearly every way to the predicate device, the ESTECH Cobra Surgical System (K051749). The only difference between the two systems is that this application requests clearance for the addition of a thermal insulation pad, known as the ThermaShield.

This SPECIAL 510(k) is being submitted only to accommodate the inclusion of the ThermaShield. Estech is not requesting any change to the Indications for Use of the ESTECH Cobra Surgical System, nor are there any technological changes being submitted for the ESTECH Cobra Surgical System.

Bench data provided in Section 18 demonstrates that the ThermaShield performs as intended and does not raise new types of safety or efficacy questions.

ESTECH concludes that the ESTECH Cobra Surgical System with ThermaShield accessory is substantially equivalent to the predicate ESTECH Cobra Surgical System.

f. Summary of Supporting Data

The bench testing supplied in Section 18 demonstrates that the ThermaShield technology is equivalent or better than surgical gloves, commonly used clinically, in thermally insulating adjacent tissues and is an improvement over having no insulation of surrounding tissues during ablation with the previously cleared COBRA Surgical System.

The patient contacting materials of the ESTECH ThermaShield technology have been demonstrated to be biocompatible, in accordance with ISO 10993: *Biological Evaluation of Medical Devices*, and the safety of the electrical design is in conformance with the pertinent sections of IEC 60601-1-2, (Second Edition, 2001), *Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests* and IEC 60601-2-2: *Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –W066-G609
Silver Spring, MD 20993-0002

Endoscopic Technologies, Inc. D/b/a Estech
c/o Mr. Tamer Ibrahim
Vice President, R&D/RA/QA
2603 Camino Ramon
Suite 100
San Ramon, CA, 94583

SEP 23 2011

Re: [510(k)] K110913
Trade/Device Name: Estech cobra surgical system with thermashield accessory
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: OCL
Dated: September 12, 2011
Received: September 12, 2011

Dear Mr. Ibrahim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use

510(k) Number (if known): K 110913

Device Name: ESTECH Cobra Surgical System with ThermaShield Accessory

Indications for Use:

The Estech Cobra Surgical System is intended for the coagulation of cardiac tissue using radiofrequency (RF) energy during cardiac surgery. The System can be used during general surgery to coagulate soft tissues. The System may also be used to coagulate blood and soft tissue to produce hemostasis.

Prescription Use __X____ AND/OR Over-The-Counter Use

_____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K110913